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(71) Applicant (for all designated States except US): LUMINEX

CORPORATION [US/US]; 12212 Technology Boulevard #K, Austin, TX 78727-6115 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): CHANDLER, Van, S. [US/US]; 2808 McKinney Avenue #410, Dallas, TX 75204 (US). FULTON, R., Jerrold [US/US]; 305 Evergreen Trail, Cedar Hill, TX 75104 (US). CHANDLER, Mark, B. [US/US]; 4 Niles Road, Austin, TX 78700 (US).

(74) Agent: PATTERSON, Melinda, L.; P.O. Box 4433, Houston, TX 77210 (US).

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(54) Title: MULTIPLEXED ANALYSIS OF CLINICAL SPECIMENS APPARATUS AND METHOD

#### (57) Abstract

A method for the multiplexed diagnostic and genetic analysis of enzymes, DNA fragments, antibodies, and other biomolecules comprises the steps of constructing an appropriately labeled beadset, exposing the beadset to a clinical sample, and analyzing the combined sample/beadset by flow cytometry is disclosed. Flow cytometric measurements are used to classify, in real-time, beads within an exposed beadset and textual explanations, based on the accumulated data obtained during real-time analysis, are generated for the user. The inventive technology enables the simultaneous, and automated, detection and interpretation of multiple biomolecules or DNA sequences in real-time while also reducing the cost of performing diagnostic and genetic assays.

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A. CLASSIFICATION OF SUBJECT MATTER IPC 6 G01N15/10 G01N3 C12Q1/68 G01N33/50 GO1N15/14 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) IPC 6 G01N C12Q Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Relevant to claim No. Category \* Citation of document, with indication, where appropriate, of the relevant passages 1-49,53 WO 93 02360 A (TRANSMED BIOTECH INCORPORATED) 4 February 1993 X 50 see page 4, line 18-31 A see page 5, line 6-10 see page 6, line 10-25 see page 6, line 26 - page 7, line 8 see page 7, line 18 - page 8, line 2 see page 9, line 31-32 see page 19, line 36 - page 20, line 2 50-52 WO 89 11101 A (MICHAEL JOHN HOLMES) 16 A November 1989 see page 5, line 20 - page 6, line 15 see page 7, line 33 - page 8, line 2 see page 8, line 15-20 -/--Patent family members are listed in annex. Further documents are listed in the continuation of box C. Special categories of cited documents: "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance invention 'E' earlier document but published on or after the international \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled document referring to an oral disclosure, use, exhibition or other means m the art. 'P' document published prior to the international filing date but later than the priority date claimed '&' document member of the same patent family Date of mailing of the international search report Date of the actual completion of the international search **-6.08.97** 28 July 1997 Name and mailing address of the ISA Authorized officer European Patent Office, P.B. 5818 Patentiaan 2 NL - 2280 HV Rijstwijk Td. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016 Zinngrebe, U

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| Box i  | Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)   |  |  |  |  |
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| This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons: |   |  |  |  |  |
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| 1.<br>3.   | . CLAIMS: 1-58,85,89 2. CLAIMS: 59-70,71,74<br>. CLAIMS: 71,74 4. CLAIMS: 75-84   |  |  |  |  |
| F  | OR FURTHER INFORMATION PLEASE SEE FORM PCT/ISA/206 MAILED 01.04.97  |  |  |  |  |
| 1. <b>X</b>  | As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.  |  |  |  |  |
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